510(k) Summary

Preparation Date
22 February 2012

Sponsor
Choice Spine, LP
400 Erin Drive
Knoxville, TN 37919
p: 865.246.3333
f: 865.588.4045

Contact
Mark Bekkala

Trade Name
Choice Spine Vertebral Body Replacement (VBR) System

Common Name
Spinal Vertebral Body Replacement Device

Regulatory Classification & Device Product Codes
888.3060
MQP – Spinal intervertebral body fixation orthosis

Predicate Devices
Alphatec Spine Novel VBR Spinal System (K050553)
Globus Medical NIKO Corpectomy Spacer (K072465)
Verticor Samson Corpectomy Cage (K091426)

Device Description
The Choice Spine Vertebral Body Replacement (VBR) System devices have a basic oval shape with a hollow center for placement of bone graft. The superior & inferior surfaces have ridges, or 'teeth' for resisting migration. The devices are available in an assortment of heights & multiple angles of lordosis to accommodate different anatomic requirements.

Intended Use

The Choice Spine Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The VBR device is intended for use with supplemental fixation & is to be used with autograft and/or allograft bone graft material.

510(k) Summary (continued)

Materials

The Choice Spine Vertebral Body Replacement (VBR) System is manufactured from Polyetheretherketone (PEEK OPTIMA® from Invibio®) per ASTM F2026. Integral radiopaque markers are manufactured from tantalum per ASTM F560.

Technological Characteristics

The Choice Spine Vertebral Body Replacement (VBR) System consists of implant devices with a range of depths, widths, heights, & angles of lordosis similar to the identified predicate systems.
The Intended Use of the Choice Spine Vertebral Body Replacement (VBR) System is identical to the predicate systems. The Choice Spine Vertebral Body Replacement (VBR) System materials are similar to the predicate systems.

Substantial Equivalence

Documentation was provided that demonstrates the Choice Spine Vertebral Body Replacement (VBR) System to be substantially equivalent to previously cleared device systems. The substantial equivalence is based upon equivalence in intended use, indications, anatomic location, materials, & performance. Mechanical testing was performed according to the guidelines outlined in ASTM F2267-04 "Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression" & ASTM F2077-03 "Test Methods for Intervertebral Body Fusion Devices". Testing parameters executed were static compression, dynamic compression, static torsion, dynamic torsion, subsidence, & expulsion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Choice Spine, LP
% Mr. Mark Bekkala
400 Erin Drive
Knoxville, Tennessee 37919

APR - 5 2012

Re: K120570
Trade/Device Name: Choice Spine Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: March 19, 2012
Received: March 20, 2012

Dear Mr. Bekkala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

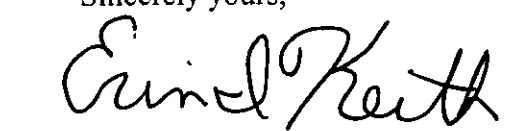
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K120570

Device Name: Choice Spine Vertebral Body Replacement (VBR) System

Indications for Use:

The Choice Spine Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The VBR device is intended for use with supplemental fixation & is to be used with autograft and/or allograft bone graft material.

Prescription Use ____X____ and/or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120570